

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

IN RE GENZYME CORP. SECURITIES LITIGATION)))))	Consolidated Case No. 09-cv-11267 (GAO) <u><i>Leave to file granted on June 21, 2012</i></u>
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**LEAD PLAINTIFFS' NOTICE OF SUPPLEMENTAL AUTHORITY IN SUPPORT
OF THEIR MOTION FOR RELIEF FROM FINAL JUDGMENT UNDER RULE 59**

Lead Plaintiffs respectfully submit this notice of supplemental authority to advise the Court of a decision by the Eighth Circuit Court of Appeals, *Public Pension Fund Group v. KV Pharm. Co.*, No. 10-3402 (8th Cir. June 4, 2012) (Exhibit A), which demonstrates this Court's error in dismissing the Complaint by reversing a key decision on which this Court relied. In reversing the holding in *Public Pension Fund Grp. v. KV Pharm. Co.*, 705 F. Supp. 2d 1088 (E.D. Mo. 2010) that FDA Forms 483 are immaterial, the Eighth Circuit *rejected* the contention that the receipt of Forms 483 can never render a company's statements about compliance with FDA regulations or CGMP false or misleading. Specifically, the Eighth Circuit held that:

[F]or purposes of pleading a securities fraud claim, the issuance of Form 483s may render a defendant's statement about its compliance with FDA regulations or cGMP false, or at least misleading, in some circumstances. The FDA's issuance of Form 483s may be material depending on a number of factors, including the number, severity, and pervasiveness of objectionable conditions noted, as well as whether a company has failed to address or correct the deficiencies noted....

KV Pharm. op. at 15.¹ The Eighth Circuit also held that the district court abused its discretion by denying the plaintiffs' post-judgment motion to amend their complaint. *KV Pharm.* op. at 27.

The circumstances that the Eighth Circuit found to demonstrate the materiality of Forms 483 in *KV Pharm.* mirror the circumstances present at Genzyme. The FDA repeatedly identified Genzyme's CGMP deficiencies at multiple inspections, but Genzyme failed to remedy those deficiencies while assuring investors that its highly-anticipated Lumizyme BLA would be approved by the FDA, and that it had satisfied FDA concerns about its compliance – even though approval of the Lumizyme BLA was contingent upon CGMP compliance at the Allston facility (where Lumizyme was to be manufactured). Just as in *KV Pharm.*, both plaintiffs and the FDA alleged that the problems documented in the Forms 483 were numerous, severe, pervasive and systemic. Complaint (ECF No. 40) at ¶¶98-101, 170, 180-86; FDA Complaint ¶¶12, 17-18. Indeed, the FDA's complaint against Genzyme used language nearly identical to that quoted in *KV Pharm.* to highlight the failure to remedy long-standing CGMP deficiencies after repeated warnings. Compare *KV Pharm.* at 16 with FDA Complaint at ¶18.

As Plaintiffs explained in their Rule 59 motion, this Court's determination that Forms 483 are immaterial led it to conclude that Defendants did not act with scienter in failing to disclose the Forms 483 and in misrepresenting both their responses to the FDA's criticisms and their ability to obtain approval of Lumizyme, which was dependent upon CGMP compliance. See Rule 59 Br. at 8-11. *KV Pharm.* now confirms that Lead Plaintiffs have

¹ The Eighth Circuit also distinguished *Acito v. IMCERA Group, Inc.*, 47 F.3d 47 (2d Cir. 1995), on which this Court also relied, observing that in *Acito* the Forms 483 at issue concerned only a small portion of the defendant's overall business. *KV Pharm.* at 17 n.9. Here, unlike in *Acito*, the problems concerned Genzyme's flagship plant.

properly alleged that the Forms 483 were material, and, consequently, that Defendants acted with scienter. For these reasons, Lead Plaintiffs' Rule 59 motion should be granted.

Dated: June 22, 2012

Respectfully submitted,

/s/ Bryan A. Wood

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CERTIFICATE OF SERVICE

I, Bryan A. Wood, hereby certify that the foregoing document, filed through the ECF System, will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF), and paper copies will be sent to those indicated as non-registered participants on June 22, 2012.

/s/ Bryan A. Wood